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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674
25226	7590	01/26/2006		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER CHANNA VAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/655,911

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of amendment and remarks dated 8-15-05 and amendment, remarks and NPL dated 11-9-05 is acknowledged.

Claims 1-24 have been examined. Claims 25-44 have been newly added. Claims 1-44 are pending in the instant application.

Newly submitted claims 25-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Instant claims are directed to a method of treating an individual in need of treatment for a capsaicin-responsive condition, which include various kinds of treatments that respond to capsaicin, other than those already examined in the instant application. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-34 have withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-24 and 34-44 are considered for examination.

### ***Claim Rejections - 35 USC § 103***

Claims 1-24 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,856,361 in view of Wholehealthmd (data sheet).

The claims are rejected for the reasons set forth in the previous prior office action.

***Response to Arguments***

Applicant's arguments filed 8-15-05 and 11-09-05 have been fully considered but they are not persuasive.

Applicants' argue that Holt et al. do not teach a composition with recited combination of components, amounts and pH, for cleansing or removal of capsaicin or another painful substance from a bodily surface cleansing. It is argued that there is no motivation in Holt for the removal of capsaicin, as it is no longer an irritant in the presence of an anesthetic agent. It is argued that the website does not provide the missing claim elements because the reference only teaches capsaicin as an irritant and not teach alleviating these effects by applying a capsaicin soluble composition. Applicants state that in accordance with the telephonic interview of 10-5-05, instant kit requires that the two components be separated. It is stated that the wholehealthmd washing hands with warm but not hot water, which does not solubilize capsaicin (evidence submitted) to the extent claimed (10% w/w) and that capsaicin requires much longer incubation with soap water.

Applicants' arguments are not persuasive because, the motivation to remove capsaicin from the exposed site or applied site does not come from Holt et al and instead comes from the data sheet. Irrespective of the solubility of capsaicin in hot or warm water, one of an ordinary skill in the art would have understood to remove the residual capsaicin from skin, after applying a capsaicin-containing composition to

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alleviate pain or any other condition that capsaicin treats. It is argued that the composition of Holt does not necessitate the removal of capsaicin with a separate cleansing composition because the inclusion of anesthetic in the composition alleviates any skin irritation caused by capsaicin; where as in the instant composition facilitates the removal of capsaicin. The argument is not persuasive because Holt et al recognizes the potential of capsaicin in relieving pain and at the same recognizes that it also causes skin burning, irritation, pruritis, itching etc. The teachings of Holt et al are also directed to reducing the side effect of capsaicin i.e., reduce irritation, burning etc. Thus absent any unexpected result, one of an ordinary skill in the art would have chosen to prevent or reduce the side effects of capsaicin by adding the second component (that reduces the side effects of capsaicin) by using them together or sequentially (one after the other) so to either neutralize capsaicin or wash it off from the skin.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

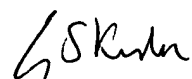
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 23, 2006



Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600